

COMMONWEALTH of VIRGINIA

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STATEWIDE STANDING ORDER

Collecting and Processing Specimens for COVID-19 Diagnostic and Screening Testing Using BinaxNOW COVID-19 Antigen Cards in K-12 Schools

Date Issued: January 14, 2022

Condition/Situation:

This order covers diagnostic testing or screening testing for school members (K-12 teachers and staff and/or students). The Abbott BinaxNOW COVID-19 Antigen (Ag) Card is a CLIA waived test; therefore, any site where this test will be performed and where this standing order will be used must have a current CLIA Certificate of Waiver, at a minimum.

<u>Diagnostic Testing</u>: School member presents requesting, and consenting to, COVID-19 diagnostic testing. Diagnostic Testing is testing performed by trained personnel on persons who have symptoms / signs suggestive of COVID-19 or who are close contacts to a person known or suspected to have COVID-19.

<u>Screening Testing</u>: Screening Testing is testing of asymptomatic persons (K12 teachers, faculty and staff or students) on a planned routine basis.

The school member shall be tested for COVID-19 based on the standing order below.

This standing order authorizes:

- Licensed health care providers in accordance with the conditions of their licensure OR specifically trained personnel under the supervision of such health care providers to:
 - Collect anterior nasal swabs or directly observe the self-collection of anterior nasal swabs for the purposes of performing point of care (POC) antigen testing for the detection of SARS-CoV-2 AND/OR
 - o Perform the POC antigen test using the swab collected from the school member
- The Centers for Disease Control and Prevention (CDC) has instructions about how a person can self-collect an anterior nasal swab (see How to Collect Anterior Nasal
 Specimen for COVID-19 Testing). The person observing self-collection shall ensure the person being tested reviews instructions with the person prior to self-collection.

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Required Training:

Any person (i.e., licensed health care provider or trained K12 personnel under the supervision of a healthcare provider) who: (1) collects anterior nasal swab specimens from school members, (2) observes the self-collection process by a school member, or (3) processes the Abbott BinaxNOW COVID-19 Antigen Cards must complete online training provided by Abbott. Training consists of watching Modules 1-4 on Abbott's training website (see https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html).

Abbott also offers interactive training webinars upon request. The VDH Testing Team can provide more information for those interested. Training-related questions can be directed to Abbott, or the VDH Testing Team at antigeninfo@vdh.virginia.gov.

Diagnostic Assessment:

Eligibility Indications—Individuals being tested should be a K-12 school member conducting or participating in in-person instruction or working at a public or private K-12 school in Virginia with symptoms/signs of COVID-19 or has been identified as a close contact to a person with known or suspected COVID-19.

Symptoms/signs of COVID-19 include fever or chills, fatigue (more tired than usual), headache, muscle aches, cough, nasal congestion or runny nose, new loss of taste or smell, sore throat, shortness of breath or difficulty breathing, abdominal pain, loss of appetite, diarrhea, nausea or vomiting. Please see the VDH Algorithm for Evaluating Non-Critical Infrastructure Workers with COVID-19 Symptoms or Exposures and the VDH Algorithm for Evaluating a Child with COVID-19 Symptoms or Exposure for more information.

Testing:

- 1. Individuals being tested should be provided a mask (if not already wearing one) and escorted or directed to the testing location via a route that will not risk exposing others. The person accompanying them should practice physical distancing and also wear a mask.
 - Testing at the school should be conducted in a private room away from others or in a separate school-affiliated building (e.g., administrative office, etc.). Drive-thru testing methods can be utilized where the person does not leave their car, if desired.
- 2. Trained personnel shall provide the Abbott BinaxNOW Patient Fact Sheet to the individual being tested prior to administering the test. Obtain written consent from the individual or if a student, from the parent/guardian as necessary.
- 3. If trained personnel are *collecting the specimen*, they will need to don (put on) appropriate personal protective equipment (PPE) before specimen collection. Appropriate PPE for anterior nasal swab specimen collection includes:

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- a. Fit-tested N95 respirator (or surgical mask if N95 respirator not available)
- b. Eye protection (face shield or full coverage goggles). "Safety glasses" are not recommended.
- c. Gloves
- d. Non-sterile gown with sleeves

The CDC document <u>Coronavirus disease 2019 (COVID-19) Factsheet</u> shows appropriate donning and doffing of PPE.

For trained personnel who are *directly observing* self-collected specimens, the observer should practice physical distancing and wear a surgical mask and gloves. People who are self-collecting anterior nasal swabs should follow CDC's instructions (see <u>How to Collect Anterior Nasal Specimen for COVID-19 Testing</u>).

- 4. Trained personnel shall follow specimen collection, specimen storage, and the testing protocol required by the manufacturer (see IN195001_rev2 v4 Abbott BinaxNOW COVID-19 Ag ProCard 20201216).
- 5. Trained personnel at testing sites shall collect the anterior nasal swab OR individual school members may self-collect the specimen while under the supervision of a trained person according to Abbott BinaxNOW COVID-19 Ag Card Product Insert and Procedure Card.
- 6. If conducting a test on an asymptomatic school member who has been identified as a close contact, calculate the number of days of quarantine to assure that testing is conducted on or after 5 to 7 full days since the date of last known contact.
- 7. After specimen collection, trained personnel shall perform the test (process the test card) according to the BinaxNOW COVID-19 <u>Antigen Card Package Insert</u> and <u>Procedure Card</u>.
- 8. Discard all contaminated waste in a biohazard waste receptacle and clean work area with 10% bleach or EPA-approved disinfectant.
- 9. Perform hand hygiene by washing hands with soap and water or using hand sanitizer with at least 60% alcohol content before and after each specimen collection and/or test administration.
- 10. School member who is tested must remain appropriately isolated until test results are available (approximately 15 minutes).
- 11. Notify school member, or parent/guardian if the school member is a minor, of test results and reference the <u>VDH COVID-19 Guidance on Isolation and Quarantine</u> to counsel accordingly. Explain to the school member to expect outreach from the local health department (if relevant) and encourage their collaboration in this confidential process. Counsel school member regarding the interpretation of test results, including counseling to continue prevention strategies such as physical distancing and mask requirements.

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- 12. Notify the school COVID-19 team members to initiate any steps for contact tracing, such as the collection of names of close contacts, which can then be provided to the local health department. Continue to follow mitigation guidance for social distancing and mask wearing protocols.
- 13. According to the federal CARES Act, all positive and negative test results must be reported to the appropriate public health authority. Results should be reported electronically to VDH at the online portal located at https://apps.vdh.virginia.gov/pocreporting/login/login.aspx.
- 14. The licensed healthcare provider or trained personnel will provide the COVID-19 test result to the school member (or to the parent/guardian if the school member is a minor). The school member or parent/guardian will be advised to follow up on this result with their or their child's primary care or regular medical provider. If the school member does not have a primary care or regular medical provider, they will be provided with information about where further care can be obtained (e.g., urgent care centers, local primary care practices, local federally qualified health centers, local free or low-cost clinics, etc.) and be advised to follow up promptly with one of these organizations.
- 15. Notification of Supervising Clinician/Licensed Healthcare Provider—Trained personnel that are not licensed health care professionals should notify the supervising licensed healthcare provider if there are: (1) questions about or difficulties in obtaining a nasal swab for point-of-care testing, (2) questions or difficulties encountered running the point of care antigen test, or (3) other testing-related questions or issues.

This order is in effect for 2 years or at the end of the FDA Emergency Use Authorization for the product, whichever is earlier.

- DocuSigned by:
Chi: M. June

Acting State Health Commissioner